



CGC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

Edward L. Carver ) Conf. No.: 9998  
Patent No. 6,812,032 )  
Serial No.: 09/039,789 ) Group Art Unit: 1743  
Filed: March 16, 1998 )  
Examiner: A. Soderquist )  
Docket No. 97406.00030 )

For: **APPARATUS FOR MAKING A PLURALITY OF REAGENT  
MIXTURES AND ANALYZING PARTICLE DISTRIBUTIONS  
OF THE REAGENT MIXTURES**

Certificate  
SEP 22 2005  
of Correction

Commissioner for Patents  
Attention: Certificate of Correction Branch  
P.O. Box 1450  
Alexandria, VA 22313

**REQUEST FOR CERTIFICATE OF CORRECTION OF  
OFFICE MISTAKE PURSUANT TO 37 C.F.R. § 1.322**

Dear Sir:

Patentee hereby requests a Certificate of Correction to be issued pursuant to the Director's authority pursuant to 35 U.S.C. 254 to correct a mistake in a patent. The mistake incurred through the fault of the Office and is clearly disclosed in the record.

Patentee respectfully requests pursuant to 37 C.F.R. § 1.322(a)(1)(i) that the Director issue a Certificate of Correction deleting an originally named inventor that is not the inventor of the invention as patented.

OCT 4 2005

A petition pursuant to 37 C.F.R. § 1.48(b) was originally filed on August 3, 1999 deleting originally named inventor David Charles DeCava. This Petition was received and acknowledged by the Office on August 9, 1999 as evidenced by the stamped postcard provided herein as Exhibit A. This petition was not acknowledged or addressed by the Examiner in the subsequent Office communications of September 30, 1999 and April 13, 2000. Therefore, a copy of the August 9, 1999 petition was re-filed on August 14, 2000, received, and acknowledged as evidenced by the stamped postcard provided herein as Exhibit B. The Change of Inventorship was also acknowledged by the Examiner in the Advisory Action of August 30, 2000.

Inexplicably, once again, the change of inventorship was not addressed by the Examiner in the Office Communication of February 14, 2001. Applicant once again addressed this omission in the response filed June 14, 2001 (see page 8). Further, yet again, the change of inventorship was not addressed by the Examiner in the Office Communication of August 9, 2001. Finally, the Examiner addressed and indicated that the inventorship was changed with the Office Communication of April 11, 2002, a copy of which is provided as Exhibit C. (Please see Item 1 on page 2). Unfortunately however, when granted and published on Nov. 2, 2004, the patent included the deleted inventor.

It is evident that the Office acknowledged receipt of the petition to correct inventorship on more than one occasion. The Examiner twice acknowledged its existence and entry. The correction to the inventorship was not made. It is evident that the mistake in the Patent was incurred through the mistake of the Office. Therefore, a Certificate of Correction is respectfully requested.

No additional fee is believed to be required; however, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our Deposit Account No. 50-3569.

Respectfully submitted,

Date: September 15, 2005

By   
Troy LaMontagne (Reg. No. 47,239)

PTO Correspondence Address:

McCarter & English, LLP  
CityPlace I  
185 Asylum Street  
Hartford, CT 06103  
Phone: (860) 275-7041  
Fax: (860) 724-3397

Doc No. 5,222,775

Edward L. Carver  
Serial No. 09/039,789

97406.00030

EXHIBIT A

CDC Tech

Assistant Commissioner for Patents, Washington, D.C. 20231

PATENT

Sir: Kindly acknowledge receipt of the following papers by stamping and returning this

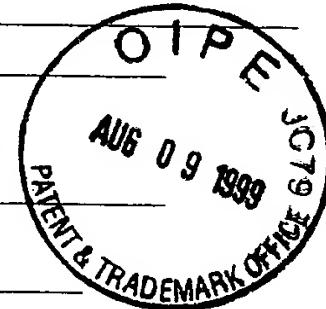
Serial No. 09/039,789 Filing Date: 3-16-98 Atty: 4492 Client No: 116310.0030

Title: Apparatus for Making a Plurality of... Due Date: 8-3-99

- A patent application including pages of abstract, specification and claims
- (Continuation) (Divisional) (CIP) (Provisional) (Design) Application
- \_\_\_\_\_ sheets of drawings  formal  informal
- Declaration of Power of Attorney  executed  unexecuted
- Assignment
- Recordation Form Cover Sheet
- Application Transmittal Letter
- Preliminary Amendment
- Amendment
- Amendment Fee Transmittal Letter
- Petition and Fee for Extension of Time
- Information Disclosure Statement
- PTO Form 1449 and Copies of Cited References
- Issue Fee Transmittal
- Submission of Formal Drawings
- Maintenance Fee
- Certificate Under 37 CFR § 373 (b)

- Verified Statement Claiming Small Entity
- Revocation And Substitute Power of Attorney
- Associate Power of Attorney
- PCT Request
- PCT Demand
- PCT Power of Attorney
- PCT Transmittal Letter to the U.S. Designated Election Office (DO/EO/US)
- Terminal Disclaimer
- Petition to Delete Inventor and Fee
- \_\_\_\_\_
- Check in the amount of \_\_\_\_\_
- Certificate of Mailing
- Certificate of Express Mailing
- No. \_\_\_\_\_
- Return postcard

Date 8-3-99



OCT 4 2005

Edward L. Carver  
Serial No. 09/039,789

97406.00030

EXHIBIT B

PATENT

Assistant Commissioner for Patents, Washington, D.C. 20231

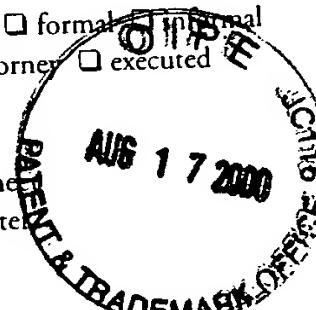
Sir: Kindly acknowledge receipt of the following papers by stamping and returning this card.

Serial No. 09,039,789 Filing Date: March 16, 98 Atty/Mgr/Empl Client No: 116310-0030

Title: Apparatus for Making a Plurality of Agent Mixtures Due Date: \_\_\_\_\_

Analyzing Article Distributions...

A patent application including pages of abstract, specification and claims  
 (Continuation) (Divisional) (CIP) (Provisional) (Design) Application  
 \_\_\_\_\_ sheets of drawings  formal  informal  
 Declaration of Power of Attorney  executed  unexecuted  
 Assignment  
 Recordation Form Cover Sheet  
 Application Transmittal Letter  
 Preliminary Amendment  
 Amendment  
 Amendment Fee Transmittal Letter  
 Petition and Fee for Extension of Time  
 Information Disclosure Statement  
 PTO Form 1449 and Copies of Cited References  
 Issue Fee Transmittal  
 Submission of Formal Drawings  
 Maintenance Fee  
 Certificate Under 37 CFR § 373 (b)



Verified Statement Claiming Small Entity  
 Revocation And Substitute Power of Attorney  
 Associate Power of Attorney  
 PCT Request  
 PCT Demand  
 PCT Power of Attorney  
 PCT Transmittal Letter to the U.S. Designated Election Office (DO/EO/US)

Petition for One Month Extension  
 Terminal Disclaimer to Obviate A Double Patenting Rejection Over A Prior Patent  
 Copy of Petition Deleting... Inventor  
 Check in the amount of \$55.00 (2 checks)  
 Certificate of Mailing  
 Certificate of Express Mailing

No. \_\_\_\_\_  
 Return postcard

Date July 1, 2000

OCT 4 2005

OCT 4 2005

Edward L. Carver  
Serial No. 09/039,789

97406.00030

EXHIBIT C



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,789	03/16/1998	EDWARD LAWRENCE CARVER JR.	4537-01-2	9998

7590 04/11/2002

ATTN: ANITA LOMARTRA  
700 STATE STREET, GRANITE SQUARE  
P.O. BOX 1960  
NEW HAVEN, CT 065091960

116310.0030

EXAMINER

SODERQUIST, ARLEN

ART UNIT

PAPER NUMBER

1743

32

DATE MAILED: 04/11/2002

RECEIVED  
APR 15 2002  
CUMMINGS & LOCKWOOD

Please find below and/or attached an Office communication concerning this application or proceeding.

44-41657-02

DOCKETED	44-41657-02
DUE DATE	7/11/02
STATUTORY DATE	10/11/02

<b>Office Action Summary</b>	<b>Application No.</b> 09/039,789	<b>Applicant(s)</b> CARVER ET AL.
	<b>Examiner</b> Arlen Soderquist	<b>Art Unit</b> 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11 February 2002.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 27-30,32-35,38 and 40-46 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 27-30,32-35,38 and 40-46 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

Art Unit: 1743

1. In view of the papers filed August 3, 1999, the inventorship in this nonprovisional application has been changed by the deletion of David Charles DeCava.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 39-45 been renumbered 40-46. Claim 39 was presented in the amendment filed February 29, 2000 and cancelled in the amendment filed August 14, 2000.

3. Claims 27-30,32-35,38 and 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making mixtures from at least two lysing agents by changing the respective volumes of the lysing agent relative to the volume of blood dependent upon the animal species of the blood, does not reasonably provide enablement for changing the lysing agent to blood volume ratio for a single lysing agent based on the type of animal species of the blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification teaches the presence of two lysing agents to make mixtures based on the animal type of the blood sample. Within the scope of these teachings, is using only one of the lysing agents to make the mixture for lysing the blood sample. However, the specification fails to teach that a single lysing agent can lyse all types of blood can by changing the blood to lysing agent volume ratio. The specification further fails to teach or provide any basis for grouping blood samples into a set or analyzing a set of blood sample types that can be lysed by changing the lysing agent to blood volume ratio of a single lysing agent. Due to the difference of blood types recognized by the art of record, one of skill in the art would not expect a single lysing

Art Unit: 1743

agent to be effective to lyse all blood types based on the teachings found in the instant specification. It also appears that a diluent is required to be present to form the lysing mixture since the lysing agents each have a constant concentration and the sensing apparatus requires a certain volume to run the analysis.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 27-30, 32-35, 38 and 40-46 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carver (US 5,316,725, newly applied). In the patent Carver teaches different compositions of lysing agents for performing white blood cell analysis. Column 13 discusses multispecies applications of the lysing agents teaching that due to variations in the physiology of the white blood cell membrane the lysing reagent composition must be optimized for each species. Table 1 shows the differences in the ratios of the two lytic agents in the composition, the amount of blood sample to the lytic composition, and the amount of diluent to the lytic composition for two species. Example 4 shows how to optimize the ratios by creating various mixtures from the individual lytic agents and diluent. In particular, table 3 shows a set of experiments in which the volume of the two lysing agents is varied. Since these experiments are being performed on an automated apparatus, the claims are anticipated. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the process since the Courts have held that providing a mechanical or automatic means to replace manual activity which accomplishes the same result is within the skill of a routineer in the art (see *In re Venner*, 120 USPQ 192 (CCPA 1958)). Applicant is reminded that affidavits or declarations, such as those submitted under 37 CFR 1.131 and 37 CFR 1.132, filed during the prosecution of a parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make copy of the original affidavit or declaration filed in the parent application.

7. Claims 27-30, 32-35, 38 and 40-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto or Cellect Hematology in view of Carver (US 5,316,725 as explained above).

In the figures and associated discussion Yamamoto teaches an automated blood analyzer and method for making blood particle analyses. Yamamoto teaches at least one pump (102, 111, 162) in fluid communication with a mixing chamber (113-115) and a source diluent. A sample (101) is removed from a sample container by a sample probe

Art Unit: 1743

(117,161) and the at least one pump transfers the sample and diluent to the mixing chambers. Since the fluid flow arrows of figures 2 and 5 show pumps 102, 111, and 162 as capable of both suction and positive pressure, they are positive displacement pumps. Two different lysing reagents (141,142) are also transferred to the mixing chambers by a vacuum pump. The blood sample is analyzed for particles through a sensing orifice (158). The device has a controller (figure 3) for controlling the device and analyzing the result. Also Figure 4 shows that the result is obtainable in around 47 seconds. Yamamoto does not teach a multiple species database having different lysing compositions for each species that are mixed for blood samples from the different species.

In the figures and associated discussion Cellect Hematology teaches a fully automated blood analyzer and method for making blood particle analyses. In the figure on pages 5 - 6 Cellect Hematology shows the major systems of the instrument including at least one positive displacement syringe pump and stepper motor in fluid communication with a mixing chamber (dilution manifold) and a source diluent. A sample is removed from a sample container by a sample probe and the at least one pump transfers the sample and diluent to the dilution manifold. A lysing reagent is also provided during an analysis. The blood sample is analyzed for particles through a sensing orifice (counting manifold). The device has a controller (microprocessor) for controlling the device and analyzing the result. On page 1 in the first column, Cellect Hematology teaches the ease in adapting the instrument to add on new tests. Cellect Hematology does not teach a multiple species database having different lysing compositions for each species that are mixed for blood samples from the different species.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Carver into the Yamamoto or Cellect Hematology devices and methods and control them to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from

Art Unit: 1743

multiple species and an optimized process including reagent sample compositions would have been required for each species as shown by Carver.

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly applied Carver reference has an inventorship that is different from the instant inventorship and clearly teaches the difference between blood of different animal species can be lysed by changing the volume ratios between the blood sample and the lysing agent based on the animal species. In this respect the previous secondary references have been dropped because although they show that different concentrations of a single lytic agent (Dixon and Halliday) will have varying affects on blood samples of different species (canine and bovine), they do not teach that the concentration differences can be obtained by varying the volume ratio of blood to lytic agent. In the Halliday reference, both methods use the same volume ratio of blood to lytic agent and difference in concentration is obtained by varying the diluent that is also added to the blood sample.

The rejection for lack of enablement arises from the fact that the instant specification fails to teach one of skill in the art how to use a single lytic agent and properly lyse blood from all animal species based on changing the blood to lytic agent volume ratio. Since this is the broadest scope of the claims, it must be enabled by the specification. Additionally it appears that a diluent is also required for the proper functioning of the device and method since it appears that the apparatus and methods described in the specification require a minimum volume or a set volume of sample/lytic agent mixture for them to function properly.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to measuring properties of animal blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination 09/039,789 CARVER ET AL.	
		Examiner	Art Unit	Page 1 of 1 Arlen Soderquist 1743

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5262329	11-1993	Carver, Jr.	436/63
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**Attachment for PTO-948 (Rev. 03/01, or earlier)**

6/18/01

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTO-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

**Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a)**

**Failure to take corrective action within the set period will result in ABANDONMENT of the application.**

OCT 4 2005  
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